REMARKS/ARGUMENTS

Applicant has carefully reviewed and considered the Final Office Action (FOA) mailed on April 28, 2011, and the references cited therewith.

Claims 1, 3, 6-7, 12-13, 16-20, and 32-33 are amended, claims 37-39 are canceled, claims 21-31 are withdrawn, and no claims are added; as a result, claims 1-36 are now pending in this application.

Examiner Interview Summary

Applicant thanks Examiner Suba Ganesan for the courtesy of a telephone interview on May 24, 2011. Applicant and Examiner Ganesan appeared to reach agreement that independent claims 1, 20, and 32-33 and the remarks, as presented herein, would overcome the rejections included in the present FOA. Applicant thanks Examiner Ganesan for her time and consideration.

§ 112 Rejection of the Claims

Claims 1-20 and 32-36 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The specification allegedly does not support defining of the radiopaque markers as a first set and a second set or describing a comparison of the radiopaque marker first set and the second set to define an orientation of the inner and outer covering of the PTFE in relation to at least one end of the framework. Applicant respectfully traverses the rejection as follows.

Applicant notes that the specification of the present application as originally submitted recites in paragraph 0033, inclusive:

> In the embodiments of FIGS. 3a-3c, the radiopaque markers are shown attached to the stent framework in the region of a strut which connects a peak 132 on one serpentine band to a trough 136 on another serpentine band. It is **also** within the scope of the invention for the radiopaque markers to be provided within or along a **circumferential band** of the stent framework.

Applicant notes that the specification of the present application as originally submitted recites in paragraph 0034, lines 3-6:

> Typically, where a plurality of markers is present, at least some of the radiopaque markers indicate at least one end of the coverings on the inner and outer surfaces and desirably both ends.

Applicant further notes that the specification of the present application as originally submitted recites in paragraph 0035, lines 1-4:

> **Additionally**, radiopaque markers may be used to denote end portions of the stent. **FIG. 7** shows an inventive stent 100 having both cover markers 160 and end markers 164.

As such, Applicant respectfully submits that the specification of the present disclosure describes that the radiopaque markers are attached to the stent framework in the region of a strut which connects a peak 132 on one serpentine band to a trough 136 on another serpentine band, where the region of the strut is covered by the covering 112. Applicant respectfully submits that the specification of the present disclosure describes that radiopaque markers can **also** be provided within or along a **circumferential band** of the stent framework, where the only circumferential band of the stent framework disclosed in the specification and figures (e.g., in Figures 1-2 and 4-7) is at one or both of the uncovered ends of the stent framework.

Moreover, Applicant respectfully submits that the specification of the present disclosure as originally submitted describes that where a plurality of markers is present, at least some of the radiopaque markers **indicate** at least one end of the coverings on the inner and outer surfaces and desirably both ends. **Additionally**, radiopaque markers may be used to **denote** end portions of the stent. Of note, Figure 7 of the present disclosure shows a stent 100 having both cover markers 160 and uncovered end markers 164, where the plurality of cover markers and the plurality of uncovered end markers provided within or along the **circumferential**

band of the stent framework are completely separated from each other by an uncovered region of the stent framework.

> Accordingly, Applicant respectfully submits that the claim language:
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> the stent further comprising at least one radiopaque marker of a **first** set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering and placed to indicate a deployed position of a covered region of the stent, the framework further comprising a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one radiopaque marker of a **second** set placed to indicate a deployed position of the uncovered region of the stent

is fully supported by the specification and figures of the present disclosure as originally submitted in such a way as to reasonably convey that the inventors, at the time the application was filed, had possession of the invention. For instance, one of ordinary skill in the relevant art would appreciate that two pluralities of radiopaque makers that are completely separated from each other by an uncovered region of the stent framework can reasonably be termed a first set and a second set of radiopaque markers.

Additionally, Applicant notes that the specification of the present application as originally submitted recites in paragraphs 0002-0003, inclusive:

> Recently, stents having coverings have been suggested for a variety of purposes including for the treatment of intracranial aneurysms. Covered stents, when used for this purpose, must be deployed with extreme precision. Typically, the covered portion of the stent must be deployed across the neck of the aneurysm, **but not** over bifurcations or side arteries.
>
> There is a need for intracranial stents with markers which are readily visualized under imaging modalities such as fluoroscopy and which are placed so as to indicate the location of a covered portion of a stent in order to facilitate the precise deployment of such a stent.

Applicant further notes that the specification of the present application as originally submitted recites in paragraph 0038, lines 1-10:

> Fig. 4 depicts a stent 100 deployed in a vessel 150 with the covering 112 of the stent 100 deployed across the neck 142 of an aneurysm 146. Uncovered regions located at the ends of the stent 100 are desirable to anchor the ends of the stent 100 beyond the aneurysm neck 142. Further, regions without covering 142 allow for continued blood flow through any bifurcations or side branch arteries 168 in proximity to the stent uncovered region. It is desirable to provide uncovered end regions sufficient to anchor the stent 100 securely.

As previously presented, Applicant respectfully submits that the specification of the present disclosure as originally submitted describes that where a plurality of markers is present, at least some of the radiopaque markers **indicate** at least one end of the coverings on the inner and outer surfaces and desirably both ends. **Additionally**, radiopaque markers may be used to **denote** end portions of the stent. Of note, Figure 7 of the present disclosure shows a stent 100 having both cover markers 160 and uncovered end markers 164, where the plurality of cover markers and the plurality of uncovered end markers provided within or along the **circumferential band** of the stent framework are completely separated from each other by an uncovered region of the stent framework.

One of ordinary skill in the relevant art would appreciate that in order to facilitate the precise deployment of such a stent, for instance, the covered portion of the stent must be deployed across the neck of the aneurysm, **but not** over bifurcations or side arteries. Accordingly, a stent can be deployed in a vessel with the covering of the stent deployed across the neck of the aneurysm and uncovered regions located at the ends of the stent can be used to anchor the ends of the stent beyond the aneurysm neck. One of ordinary skill in the relevant art would appreciate that a major purpose for providing a first set of radiopaque markers disposed between the inner covering and the outer covering and providing a second set of radiopaque markers along a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework would be that a comparison of the first set and the second set defines an orientation of the inner and outer covering of the PTFE in relation to the at least one end of the framework.

Claims 3-7 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses the rejection as follows.

Applicant has amended claims 3 and 6-7 to overcome the § 112 rejection thereof.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 112 rejection of claims 1-20 and 32-36.

§ 103 Rejection of the Claims

Claims 1-20 and 32-36 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Wijay (U.S. Patent No. 6,340,366) in view of Edwin, et al. (U.S. Publication No. 2002/0095205) and Ventura (U.S. Publication No. 2004/0044399), with supporting evidence from Wolinsky (U.S. Patent No. 6,331,189). Applicant respectfully traverses the rejection as follows.

Applicant does not admit that the either the Edwin reference or the Ventura reference is indeed prior art and reserves the right to swear behind at a future date. Nonetheless, in the interest of advancing prosecution of the claims of the present application, Applicant respectfully submits that the claims are patentably distinguishable from the teachings of the reference cited in the present FOA for at least the following reasons.

Applicant notes that the Wijay reference appears to teach a "stent with nested or overlapping rings". (Title). The Edwin reference appears to teach, "encapsulated radiopaque markers". (Title). The Ventura reference appears to teach, "radiopaque links for self-expanding stents". (Title). Applicant further notes that the Wolinsky reference appears to teach a "flexible medical stent". (Title).

However, following review of the Wijay, Edwin, Ventura, and Wolinsky references, Applicant respectfully submits that the references, individually or in combination, do not teach, suggest, or render obvious a stent including a single

tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts including a plurality of serpentine bands and further including a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, where the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and where the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further including an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker of a **first** set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering and placed to indicate a deployed position of a covered region of the stent, the framework further comprising a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one radiopaque marker of a **second** set placed to indicate a deployed position of the uncovered region of the stent.

In contrast, Applicant's independent claim 1, as currently amended, presently recites:

> A stent comprising a single tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in

opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and wherein the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguousthe stent further comprising at least one radiopaque marker of a **first** set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering and placed to indicate a deployed position of a covered region of the stent, the framework further comprising a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one radiopaque marker of a **second** set placed to indicate a deployed position of the uncovered region of the stent.

Independent claim 20, as currently amended, presently recites:

A stent comprising a single tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and wherein the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer cover extending along at least a portion of the outer surface of the framework, at least a portion of the inner and outer coverings being contiguous, the generally linear connector strut having at least one marker of a **first** set which is radiopaque or which may be visualized using magnetic resonance imaging, the marker of the first set directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner coverings and the outer coverings and placed to indicate a deployed

position of a covered region of the stent, the framework further comprising a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one radiopaque marker of a **second** set placed to indicate a deployed position of the uncovered region of the stent.

Independent claim 32, as currently amended, presently recites in part:

at least one radiopaque marker located within the **first** marker region of said framework, the marker directly and only attached to the plurality of serpentine bands at the generally linear connector strut and placed to indicate a deployed position of a covered region of the stent;

a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one radiopaque marker of a **second** marker region placed to indicate a deployed position of the uncovered region of the stent;

In addition, independent claim 33, as currently amended, presently recites:

A stent comprising a single tubular expandable framework having an outer surface and an inner surface, the tubular expandable framework comprising a plurality of serpentine bands, immediately adjacent serpentine bands having axially aligned and connected oppositely pointing apices such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, wherein the oppositely pointing apices reduce a distance between the immediately adjacent serpentine bands, said framework further including linear connecting members connecting at least some of said oppositely pointing apices of the immediately adjacent serpentine bands, an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker of a **first** set that is directly and only attached to the plurality of serpentine bands at the generally linear connecting members and disposed between the inner covering and the outer covering and placed to indicate a deployed position of a covered region of the stent, the framework further comprising a circumferential non-serpentine band at at least one distal end of an uncovered region of the framework comprising at least one

radiopaque marker of a **second** set placed to indicate a deployed position of the uncovered region of the stent.

As such, Applicant respectfully submits that the Wijay, Edwin, Ventura, and Wolinsky references, individually or in combination, do not teach, suggest, or render obvious each and every element and limitation of Applicant's independent claims 1, 20, and 32-33, as currently amended. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 103 rejection of independent claims 1, 20, and 32-33, as currently amended, as well as those claims that depend therefrom.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's below listed attorney at 612-236-0126 to facilitate prosecution of this matter.

CERTIFICATE UNDER 37 CFR 51.8: The undersigned hereby certifies that this correspondence is being electronically filed with the United States Patent and Trademark Office on this 26th day of May, 2011

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Date: May 26, 2011